

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL NO. 1456
LITIGATION)	Civil Action No. 01-12257-PBS
)	Subcategory Case No: 03-10643-PBS
THIS DOCUMENT RELATES TO:)	
)	Judge Patti B. Saris
<i>The City of New York, et al.</i>)	
)	
v.)	
)	
<i>Abbott Laboratories, et al.</i>)	
)	

**PLAINTIFFS’ REPLY TO DEFENDANTS’ RESPONSE TO THE SUPPLEMENTAL
BRIEF OF THE UNITED STATES ON THE FEDERAL UPPER LIMIT**

I.

Defendants’ Response to the Supplemental Brief of the United States on the Federal Upper Limit (“Defendants’ Response”) [Docket No. 6751] is silent on the following indisputable (and undisputed) fact: Whether the FUL-setting process was entirely manual or entirely automated or a mix of both, it always depended on the data defendants supplied and that data was false. This fact, by itself, renders defendants liable for violation of N.Y. Soc. Serv. L. §145-b (“Section 145-b”) which punishes even the attempt to obtain artificially inflated payments on behalf of one’s self or others. *See* plaintiffs’ reply memorandum of law in support of motion for partial summary judgment on issues relating to the Federal Upper Limit and under New York Social Services Law §145-b (“Pl. FUL Reply”) [Docket No. 6223]. Plaintiffs’ motion for partial summary judgment on Section 145-b liability should be granted.

Defendants' Response makes no contact with other material facts. Defendants Response does not deny that their false prices created a fictional alternative universe in which CMS was forced to operate. *See* plaintiffs' memorandum of law in support of motion for partial summary judgment on issues relating to the Federal Upper Limit and under New York Social Services Law § 145-b ("Pl. FUL Mem.") [Docket No. 6077] at 20. It does not deny that even where CMS exercised discretion, CMS was (to borrow the Court's phrase) "not throwing darts" (Hearing Tr., dated July 8, 2009, at 76:16-22). It does not deny that CMS always used a manufacturer price to set the FUL (*see* Gaston Declaration, attached as Exh. C to the Declaration of Joanne M. Cicala in support of plaintiffs' reply in support of motion for partial summary judgment, ("Gaston Dec.") at ¶3-4) and always worked its way up from the lowest price on the FULs Print Out. *See* Hearing Tr., dated July 8, 2009, at 76:16-22. In short, and given the foregoing, "defendants submitted false and or inflated *published* prices which, if truthful, would likely have affected the FUL." *In re Pharm. Indus. Average Wholesale Price Litig.* 498 F. Supp. 2d 402, 405 (D. Mass 2007) (emphasis in original).

Rather than address the critical points, defendants attempt to distract with extensive argument about how the United States Supplemental Brief confirms that the CMS procedure was "manually intensive" and not "mechanistic". This is not a defense to Section 145-b liability as defendants must know since they cite no legal authority in support. Section 145-b liability attaches when one attempts to obtain payment of public funds by causing data to be published that are false. *See* N.Y. Soc. Serv. L. § 145-

b(1)(a). Plaintiffs' prior submissions firmly establish this is precisely what defendants here did. *See* Pl. FUL Mem. at 14-17; plaintiffs' memorandum of law in opposition to defendants' joint motion for summary judgment on plaintiffs' "FUL fraud" claims and in further support of plaintiffs' motion for partial summary judgment on their 145-b claim ("Pl. FUL Opp.") [Dkt. No. 6147] at 10; Pl. FUL Reply at 4-5.

Defendants argue that CMS' approach means that damages are speculative. Defendants' Response at 5. First, the argument is irrelevant entirely to the question of liability under Section 145-b(1)(a), as stated above and in plaintiffs' prior submissions. As stated during Oral Argument and in plaintiffs' prior submissions, plaintiffs are eager to supply expert affidavits and briefing on FUL damage issues once the predicate liability finding is entered (or, of course, at the Court's request). Second, contrary to defendants' assertion, damages may readily be calculated. Section 145-b provides that

2. For *any violation of subdivision one*, the local social services district or the state *shall have a right to recover civil damages equal to three times the amount by which any figure is falsely overstated*" (emphasis supplied.)

Thus damages may be determined as the difference between defendants' true prices and the false prices they caused to be published.¹

¹ Given the record evidence that defendants' WAC and AWP's do not represent actual prices, it is possible that they may be treated as "non-monetary false statements or representations" under Section 145-b. In that case, damages could be measured as three times the difference between what the FUL was and what it should have been, or five thousand dollars per violation, whichever is greater. N.Y. Soc. Serv. L. §145-b(2).

Third, in those cases where CMS followed the “Simple Rule”, damages could easily be determined by the difference between what the FUL would have been had the truth been reported, and what it was based on defendants’ lies. And fourth, as discussed in plaintiffs’ prior submissions, uncertainty involved in the calculation of damages is no bar to their award. *See* Pl. FUL Opp. at 15-19.

Furthermore, even in the absence of calculable damages, Section 145-b(4)(b) also provides for penalties for false claims.

4.(b) In addition, the department of health is also authorized to recover any overpayment, unauthorized payment, or otherwise inappropriate payment ***and impose a monetary penalty against any person, or persons***, other than a recipient of an item or service under the medical assistance program, ***who caused the overpayment, unauthorized payment, or otherwise inappropriate payment to be received by the other person or persons***. All of the foregoing actions may be taken by the department of health for the same claim. (Emphasis added.)²

As there is little case law on this topic in New York, it is instructive to look at the penalty provisions of the Federal False Claims Act (“FCA”). It is well established that under the FCA the government can recover civil penalties without proving any damages. *See United States ex rel. Luther v. Consolidated Industries, Inc.*, 720 F. Supp. 919, 922 (N.D. Ala. 1989); *United States v. Rapoport*, 514 F. Supp. 519, 523 (S.D.N.Y. 1981); *United States v. Hughes*, 585 F.2d 284 (7th Cir. 1978); *Fleming v. United States*, 336 F.2d

² Note that the imposition of penalties is *in addition* to damages.

475, 480 (10th Cir. 1964), *cert. denied*, 380 U.S. 907, 85 S. Ct. 889, 13 L. Ed. 2d 795 (1965).

Civil penalties are independent from damages. “Even if no payment was made on a claim or the government cannot prove actual damages, a forfeiture shall be awarded on each false claim submitted.” *United States v. Killough*, 848 F.2d 1523, 1533-34 (11th Cir. 1988). Furthermore, as in the case of Section 145-b, proof of damages is not even necessary to establish liability under the FCA:

“Proof of damage to the Government resulting from a false claim is not a necessary part of the Government’s case under the Act. If damage is proved by the Government, as it was in the instant case as to one of Fleming’s false claims, it is entitled to recover double the amount so proved in addition to the \$2,000 forfeiture, but upon adequate proof of the making of a claim upon the Government, knowing it to be false, the United States is entitled, without proof of damage, to recover the forfeiture.” Fleming, 336 F.2d at 480 (emphasis added).

In fact, difficulty in assessing damages is no bar to either liability under the FCA or to obtaining civil penalties. ***“Nor is the fact that the dollar amount of the damages might be hard to calculate an obstacle to Relator’s claim for statutory penalties.*** The entitlement to a penalty follows from the making of a false claim, not its amount. ***One who presents a false claim becomes liable for the civil penalty*** (regardless of the amount of the false claim) . . .” *Romano*, 426 F. Supp. 2d at 180 (emphasis added).

The foregoing makes clear that defendants’ damage-related arguments provide them no defense whatsoever to liability under Section 145-b.

It is worth reminding that *truth* is a defense to Section 145-b liability. But, Defendants' Response (like every filing before it) says nothing about truth. How could it when every single AWP and WAC the FUL Defendants caused to be published was entirely false, utterly untethered to reality and grossly inflated. These predicate facts, *which defendants have known all along*, confirm the propriety of the relief sought by plaintiffs' motion.

II.

While legally irrelevant to the question of defendants' 145-b liability, Defendants' Response grossly overstates the "manually intensive" nature of the FUL setting process, as any fair read of the record (including the US Supplemental Brief, supporting affidavits and exhibits thereto) makes evident. Defendants' Response ignores that "since at least 1993, CMS has used a computerized systems to assist in setting FULs" and that "while the technologies have become more sophisticated over time, *their basic logic has not changed significantly*". Declaration of Dona M. Coffman, dated November 25, 2009 ("Coffman Dec.") at 3, 19-20 (emphasis added). Defendants' Response ignores that this computerized system (known as the "FULs System"), at all time relevant hereto,

1. Gathered pricing information from the publishing compendia and the FDA Orange Book pursuant to systematized processing logic; *see* Coffman Dec. at ¶¶ 4, 8-9, 14 and attachments A and B thereto;

2. Applied the Orange Book data to the compendia data to ensure that all drugs which have received FDA approval are included and that all drugs which have lost their FDA approval are exclude; *see id.* at ¶¶ 4, 9;

3. Obtained limited information from the CMS Rebate database pursuant to a systemized processing logic to ensure that only prices associated with manufacturers who

have effective rebate agreements are considered; *see id.* at ¶¶ 4, 11 and attachment B thereto (FULs Processing Logic);

4. Organized the data into groups of drug products having the same ingredient, strength, dosage, form, route of administration; *see id.* at ¶¶ 5, 9 and attachment B thereto (FULs Processing Logic);

5. Excluded products manufactured by companies who do not have effective Medicaid rebate agreements; *see id.* at ¶¶ 4, 11 and attachment B thereto (FULs Processing Logic);

6. Processed compendia data to remove inactive or obsolete NDCs; *see id.* at ¶ 14, and attachment B thereto (FULs Processing Logic);

7. Matched the processed Compendia data against the existing FULs System database in order to update the database records; *see id.* at ¶¶ 14-15, and attachment B thereto (FULs Processing Logic);

8. Generated a FULs Print Out for manual review to ensure compliance with CMS's program objectives; *see id.*

Defendants try to distract from this systematic big picture (which confirms that CMS was always and only using false and inflated Manufacturer Prices to set the FUL) with immaterial details and misleading statements. For example, defendants say that plaintiffs' motion fails because "after the FULs computer system produces its output, 'the FULs analyst manually reviews the FULs system to ensure that the final FUL is consistent with CMS's program objectives". Defendants' Response at 2. But there is no law to support the proposition that this entirely non-controversial activity (human review of computerized output to ensure program objectives are met) absolves defendants' of liability under Section 145-b for polluting the pricing arrays to begin with. Indeed, the FULs analysts have testified (and defendants do not contest) that if a price were important to the determination of a FUL, the FULs analyst typically *contacted the*

manufacturers to verify the price was valid and that the product was widely available in the market. *See, e.g.*, U.S. Supplemental Brief at 8; Gaston Dec. at ¶ 4. It always came down to manufacturer prices as confirmed by the manufacturers.

Defendants try to make hay of the fact that the FULs System Database did not contain Medispan WACs. Defendants' Response at 6. But Defendants know this is entirely irrelevant because CMS indisputably had defendants' WACs from FDB and Redbook and defendants had only one WAC in place at any given time for any NDC. It is misleading to suggest that CMS' failure to have in its possession yet another set of the exact same defendants' prices from Medispan is material to anything.³ *See* Pl. FUL Reply at 6-7.

III.

Defendants disregard the scope of the United States' supplemental submission and improperly re-hash ineffective arguments about AMP. Plaintiffs respectfully submit that the Court should not consider this additional argument as it extends beyond the contours of the United States' filing. To the extent the Court does permit this additional argument, however, plaintiffs response follows.

Defendants argue that because AMP is a net price, CMS knew that WAC was a list price. The argument is unsupported by the record before this Court (*see* Pl. FUL

³Also, while Defendants complain about the lack of Medispan WACs, it is the reporting of false prices -- whether a WAC or an AWP -- that created the fictional alternative universe in which CMS was forced to operate and triggers liability under 145(b). *See infra* at 2; Pl. FUL Mem. [Dkt. No.6077] at 6-10; 13-18; *see also, e.g., Commonwealth of Massachusetts v. Mylan Labs.*,

Reply at 9), including the new materials to which defendants advert in their Response⁴, and the Court's decision in *Massachusetts v. Mylan*. See *Mass. v. Mylan Labs.*, 608 F.Supp.2d 127, 156 (D.Mass. 2008).

Moreover, even if CMS knew that defendants' WACs were list prices (and again, the record does not establish this) the material question then becomes whether defendants' WACs were *truthful* list prices. This Court instructs that the veracity of defendants' WACs may be evaluated through the WAC List Price test (a test embraced by defendants only when convenient). See Pl. FUL Reply at. 4. That test says that a defendants' WAC is accurate when more than 50% of defendants' sales took place within 5% of WAC. See Pl. FUL Opp. at 4, n. 4. Defendants here know that everyone of their WACs fail the WAC list price test. That is why they did not present the results of such a test to this Court in the context of this motion practice. See Pl. FUL Reply at 5. Thus, even if the Court accepts defendants' argument that CMS knew WACs were list prices, defendants still lose because they were still obliged to report *truthful* list prices and, as defendants know, they did not.

Furthermore, defendants' argument that CMS could not have set FULs in the belief that defendants' WACs were the "lowest selling prices" has no relevance in the

608 F.Supp.2d 127 at Fn 4 (D.Mass. 2008)("Mylan")(noting impact on FUL if Par reported a truthful AWP).

⁴ The 1992 OIG Report that defendants now introduce says absolutely nothing about "list prices" or "WAC" or "wholesale acquisition cost". It concerns the calculation of AMP. The report refers to "Catalog Prices" and "Gross Sales Prices" but it is entirely unclear what either means within the context of the Report. In short, the Report carries no legal freight whatever for defendants.

context of analyzing Section 145-b liability. The question under Section 145-b is whether defendants submitted false information to obtain or in an attempt to obtain payment from public source. Defendants did this. Their WACs (whether list prices or not) were false. Hence, defendants are liable under Section 145-b.

Nor is defendants' argument relevant in the context of Section 145-b damages. Damages are measured by the difference between the false WAC that defendants reported, and a true WAC. *See* N.Y. Soc. Serv. L. § 145-b(2)

IV.

Finally, nothing in Defendants' Response alters the fact that their motion for summary judgment must be denied for the reasons set forth at length in Plaintiffs' FUL Opposition. There remains absolutely no record evidence that CMS or New York knew defendants' pricing was entirely untethered to reality or that CMS or New York agreed to set FULs or use FULs for reimbursement notwithstanding this knowledge. *See* Pl. FUL Reply at 8-10; Pl. FUL Opp. at 5-6, 11, 14. The absence of any record on this point is telling given that defendants took depositions of 31 federal government witnesses and had years for FUL related discovery. *See* Exhibit A attached hereto (previously filed as Exhibit A to the Declaration of Joanne M. Cicala in Support of the City of New York and New York Counties' Response and Objection to the Motion to Approve the Proposed Settlement between California, Florida, Ven-A-Care on behalf of Itself and the United

States and Schering-Plough, Schering and Warrick [Docket No. 6435]); *see also* CMO 33, entered September 14, 2007, at ¶ 5.

CONCLUSION

For all the foregoing reasons, plaintiffs again respectfully submit that their motion for partial summary judgment should be granted and defendants' motion should be denied.

Dated: December 16, 2009

Respectfully submitted,

**City of New York and New York Counties in
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CERTIFICATE OF SERVICE

I, James P. Carroll Jr., hereby certify that I caused a true and correct copy of the foregoing **PLAINTIFFS' REPLY TO DEFENDANTS' RESPONSE TO THE SUPPLEMENTAL BRIEF OF THE UNITED STATES ON THE FEDERAL UPPER LIMIT** to be served on counsel of record via electronic service pursuant to paragraph 11 of Case Management Order No. 2, by sending a copy to LexisNexis File and Serve for posting and notification to all parties.

Dated: December 16, 2009

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